IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	§		
John Eric Tkaczyk et al.	§	Group Art Unit:	3626
	§		
Serial No.: 10/065,159	§	Examiner:	Nguyen, Tran N.
	§		
Filed: September 23, 2002	§	Confirmation:	4870
	§		
For: METHODS AND SYSTEMS FOR MANAGING CLINICAL RESEARCH INFORMATION	§	Atty. Docket:	RD28334-1/YOD/LIU GERD:0205

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September 1, 2008	/Patrick S. Yoder/
Date	Patrick S. Yoder

RESPONSE TO NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF AND APPEAL BRIEF PURSUANT TO 37 C.F.R. §§ 41.31 AND 41.37

This Appeal Brief is being filed in furtherance to the Notice of Appeal electronically filed with and received by the Patent Office on May 27, 2008. This Appeal Brief is revised in response to the Notice of Non-Compliant Appeal Brief mailed August 1, 2008. In particular, Appellants revised Section 4 ("Status of Amendments") of the Appeal Brief to provide additional clarification with regard to the status of a previously submitted after-final amendment.

The Commissioner is authorized to charge the requisite fee of $510.00, and any additional fees which may be necessary to advance prosecution of the present application, to Deposit Account No. 07-0868, Order No. RD28334-1/YOD (GERD:0205). Appellants

note that this authorized charge may have been made upon receipt of the original Appeal Brief (deemed to be non-compliant). Thus, if the requisite charges have already been made, Appellants respectfully request that the Office forego any further charges regarding the submission of this Appeal Brief.

1. REAL PARTY IN INTEREST

The real party in interest is General Electric Company, the Assignee of the above-referenced application by virtue of the Assignment to General Electric Company by John Eric Tkaczyk, Maria Iatrou, and Naresh Kesavan Rao, recorded at reel 013111, frame 0866, and dated September 23, 2002. Accordingly, General Electric Company, as the Assignee of the above-referenced application, will be directly affected by the Board's decision in the pending Appeal.

2. RELATED APPEALS AND INTERFERENCES

The Appellants are unaware of any other appeals or interferences related to this Appeal. The undersigned is the Appellants' legal representative in this Appeal.

3. STATUS OF CLAIMS

Claims 1-40 are currently pending, are currently under final rejection and, thus, are the subject of this Appeal.

4. STATUS OF AMENDMENTS

Claims 1 and 14 were amended in a submission filed by Appellants on January 26, 2008, in response to the Final Office Action mailed November 28, 2008. This amendment was made to provide clarification with regard to certain features that were rejected by the Examiner under 35 U.S.C. § 112, second paragraph, as being indefinite. Despite the finality of the Section 112 rejections, Appellants note that these rejections were not made in the prior non-final Office Action mailed June 21, 2007, and were in fact only raised for the first

time in the Final Office Action. Thus, it would be unfair for the Examiner to refuse entry of these amendments.

Following the submission of the above-mentioned amendment, the Examiner indicated in the Advisory Action mailed February 11, 2008 that the amendment was considered and entered and that certain aspects of the Section 112 rejections have been overcome, as will be discussed in further detail below. *See* Advisory Action, pages 1-2. As such, this amendment is reflected in Appellants' Appendix of Claims on Appeal.

5. SUMMARY OF CLAIMED SUBJECT MATTER

The invention relates generally to clinical research and, more particularly, to network-based methods and systems for managing clinical research information. *See* Application, paragraph 1.

The Application contains five independent claims, namely, claims 1, 14, 17, 30, and 33, all of which are the subject of this Appeal. The subject matter of these claims is summarized below.

With regard to the aspect of the invention set forth in independent claim 1, discussions of the recited features of claim 1 can be found at least in the below cited locations of the specification and drawings. An exemplary embodiment of claim 1 provides a method for managing clinical study (CS) information (*e.g.*, 92) for a clinical research entity via a server system (*e.g.*, 12) coupled to a centralized database (*e.g.*, 20) and at least one client system (*e.g.*, 14). *See, e.g., id.* at paragraphs 15-17, 20; Figs. 1-4. The method includes receiving (*e.g.*, via receiving component 70) at the server system (*e.g.*, 12) CS information (*e.g.*, 92) relating to at least one patient (*e.g.*, 112) involved in a clinical study (*e.g.*, 94), the CS information (*e.g.*, 92) being entered through a user selected template (*e.g.*, standardized template implemented via Java™ servlet) displayed on the client system (*e.g.*, 14), wherein the user selected template is selected from a

plurality of templates stored in a centralized database (*e.g.*, 20), each of the plurality of templates configured to correspond to specific clinical studies (*e.g.*, 94). *See, e.g., id.* at paragraphs 15, 26-27, 35-37; Figs. 1-3. The method further includes storing (*e.g.*, in data storage devices 34) CS information (*e.g.*, 92) received at the server system (*e.g.*, 12) in the centralized database (*e.g.*, 20). *See, e.g., id.* at paragraphs 15-17, 33, 43; Figs. 1-3. The method further includes tracking (*e.g.*, via tracking component 66) CS information (*e.g.*, 92) stored in the centralized database (*e.g.*, 20). *See, e.g., id.* at paragraphs 15-16, 28, 32 & 35; Figs. 1-3. Additionally, the method includes updating the centralized database (*e.g.*, 20) periodically with newly received information to maintain CS information (*e.g.*, 92). *See, e.g., id.* at paragraphs 15-16, 36-38; Figs. 1-4. Finally, the method includes providing (*e.g.*, step 280, via providing component 90) CS information (*e.g.*, 92) in response to an inquiry (*e.g.*, request received at step 252). *See, e.g., id.* at paragraphs 29-32, 41-43; Figs. 3-4.

Next, with regard to the aspect of the invention set forth in independent claim 14, discussions of the recited features of claim 14 can be found at least in the below cited locations of the specification and drawings. An exemplary embodiment of claim 14 provides a method for managing clinical study (CS) information (*e.g.*, 92) for a clinical research entity via a server system (*e.g.*, 12) coupled to a centralized database (*e.g.*, 20) and at least one client system (*e.g.*, 14), the at least one client system (*e.g.*, 14) in communication with at least one medical device (*e.g.*, 58). *See, e.g., id.* at paragraphs 15-17, 20, 27; Figs. 1-4. The method includes using a template selected by a user from a plurality of templates stored in a centralized database (*e.g.*, 20) to gather protocols (*e.g.*, 116, 118) for acquisition of image data via the at least one medical device (*e.g.*, 58), each of the plurality of templates configured to correspond to specific clinical studies (*e.g.*, 94). *See, e.g., id.* at paragraphs 15, 26-27, 33-37; Figs. 1-3. The method further includes operating the at least one medical device (*e.g.*, 58) for acquiring image data based on the entered protocols (*e.g.*, 116, 118). *See, e.g., id.* at paragraphs 27, 33-34; Figs. 2-3. The method further includes receiving at the server system (*e.g.*, 12) CS information (*e.g.*, 92)

that relates to at least one patient (*e.g.*, 112) involved in a clinical study (*e.g.*, 94), the CS information (*e.g.*, 92) being entered through the user selected template displayed on the client system (*e.g.*, 14) and being generated as part of the operation of the at least one medical device (*e.g.*, 58) including acquisition of diagnostic images (*e.g.*, 120, 122, 124). *See, e.g., id.* at paragraphs 26-27, 33-37; Figs. 2-3. Additionally, the method includes storing (*e.g.*, in data storage devices 34) CS information (*e.g.*, 92) received at the server system (*e.g.*, 12) in the centralized database (*e.g.*, 20), tracking (*e.g.*, via tracking component 66) CS information (*e.g.*, 92) stored in the centralized database (*e.g.*, 20), updating the centralized database (*e.g.*, 20) periodically with newly received CS information to maintain CS information (*e.g.*, 92), and providing (*e.g.*, step 280, via providing component 90) CS information (*e.g.*, 92) in response to an inquiry (*e.g.*, request received at step 252). *See, e.g., id.* at paragraphs 15-17, 28-33, 35-37, 41-43; Figs 1-4. Finally, the method includes transmitting (*e.g.*, step 282) from the server system (*e.g.*, 12) to the at least one client system (*e.g.*, 14) at least one report relating to CS information (*e.g.*, 92) and findings (*e.g.* 120) for at least one of a clinical study (*e.g.*, 94) and a patient (*e.g.*, 112) involved in a clinical study. *See, e.g., id.* at paragraphs 15, 30-31, 42-43; Figs. 2-4.

Next, with regard to the aspect of the invention set forth in independent claim 17, discussions of the recited features of claim 17 can be found at least in the below cited locations of the specification and drawings. An exemplary embodiment of claim 17 provides a network-based system (*e.g.*, Clinical Research Coordination System (CRCS) 10) managing clinical study (CS) information (*e.g.*, 92). *See, e.g., id.* at paragraphs 14-15, 20-21; Figs. 1-3. The system (*e.g.*, 10) includes a client system (*e.g.*, 14) including a browser. *See, e.g., id.* at paragraphs 21-24; Fig. 2. The system (*e.g.*, 10) further includes a centralized database (*e.g.*, 20) for storing CS information (*e.g.*, 92) and a plurality of templates. *See, e.g., id.* at paragraph 15, 20, 26, 35-37; Figs. 1-3. The system (*e.g.*, 10) further includes a server system (*e.g.*, 12) configured to be coupled to both the client system (*e.g.*, 14) and the database (*e.g.*, 20). *See, e.g., id.* at paragraphs 20, 21; Figs. 1-2.

The server system (*e.g.*, 12) is configured to receive CS information (*e.g.*, 92) relating to at least one patient (*e.g.*, 112) involved in a clinical study (*e.g.*, 94), the CS information (*e.g.*, 92) being entered through a user selected template displayed on the client system (*e.g.*, 14), wherein the user selected template is selected from the plurality of templates stored in the centralized database (*e.g.*, 20), each of the plurality of templates configured to correspond to specific clinical studies (*e.g.*, 94). *See, e.g., id.* at paragraphs 15, 26-27, 35-37; Figs. 1-3. The server system (*e.g.*, 12) is further configured to store (*e.g.*, in data storage devices 34) CS information (*e.g.*, 92) in the centralized database (*e.g.*, 20), track (*e.g.*, via tracking component 66) CS information (*e.g.*, 92), update the centralized database (*e.g.*, 20) periodically with newly received CS information to maintain CS information, and provide (*e.g.*, step 280, via providing component 90) CS information (*e.g.*, 92) in response to an inquiry (*e.g.*, request received at step 252) by a user. *See, e.g., id.* at paragraphs 15-17, 28-33, 35-38, 41-43; Figs. 1-4.

Next, with regard to the aspect of the invention set forth in independent claim 30, discussions of the recited features of claim 30 can be found at least in the below cited locations of the specification and drawings. An exemplary embodiment of claim 30 provides a network based system (*e.g.*, Clinical Research Coordination System (CRCS) 10) for managing clinical study (CS) information (*e.g.*, 92). *See, e.g., id.* at paragraphs 14-15, 20-21; Figs. 1-3. The system (*e.g.*, 10) includes a client system (*e.g.*, 14) including a browser. *See, e.g., id.* at paragraphs 21-24; Fig. 2. The system (*e.g.*, 10) further includes at least one medical device (*e.g.*, 58) in communication with the client system (*e.g.*, 14). *See, e.g., id.* at paragraphs 26-27; Fig. 2. The system (*e.g.*, 10) further includes a centralized database (*e.g.*, 20) for storing CS information (*e.g.*, 92) and a plurality of templates. *See, e.g., id.* at paragraphs 26-27, 35-37; Figs. 1-3. The system (*e.g.*, 10) further includes a server system (*e.g.*, 12) configured to be coupled to the client system (*e.g.*, 14) and the database (*e.g.*, 20). *See, e.g., id.* at paragraphs 20, 21; Figs. 1-2. The server system (*e.g.*, 12) is configured to use a template selected by a user from the plurality of templates stored in the centralized database (*e.g.*, 20) to gather protocols (*e.g.*,

116, 118) for acquisition of image data (*e.g.*, 122, 124) via the at least one medical device (*e.g.*, 58), each of the plurality of templates configured to correspond to specific clinical studies (*e.g.*, 94). *See, e.g., id.* at paragraphs 15, 26-27, 33-37; Figs. 1-3. The server system (*e.g.*, 12) is further configured to operate the at least one medical device (*e.g.*, 58) for acquiring image data (*e.g.*, 122, 124) based on the entered protocols (*e.g.*, 116, 118). *See, e.g., id.* at paragraphs 27, 33-34; Figs. 2-3. Still further, the server system (*e.g.*, 12) is configured to receive CS information (*e.g.*, 92) relating to at least one patient (*e.g.*, 112) involved in a clinical study (*e.g.*, 94), the CS information (*e.g.*, 92) entered through a user selected template displayed on the client system (*e.g.*, 14) and generated as part of the operation of the at least one medical device (*e.g.*, 58) including acquisition of diagnostic images (*e.g.*, 120, 122, 124). *See, e.g., id.* at paragraphs 26-27, 33-37; Figs. 2-3. Additionally, the server system (*e.g.*, 12) is configured to store (*e.g.*, in data storage devices 34) CS information (*e.g.*, 92) in the centralized database (*e.g.*, 20), track (*e.g.*, via tracking component 66) the CS information (*e.g.*, 92), update the centralized database (*e.g.*, 20) periodically with newly received CS information (*e.g.*, 92) to maintain CS information (*e.g.*, 20), and provide (*e.g.*, step 280, via providing component 90) CS information (*e.g.*, 92) in response to an inquiry (*e.g.*, request received at step 252). *See, e.g., id.* at paragraphs 15-17, 28-33, 35-37, 42-43; Figs. 1-4. Finally, the server system (*e.g.*, 12) is configured to transmit (*e.g.*, step 282) to the client system (*e.g.*, 14) at least one report relating to CS information (*e.g.*, 92) and findings for at least one of a clinical study (*e.g.*, 94) and a patient (*e.g.*, 112) involved in a clinical study (*e.g.*, 94). *See, e.g., id.* at paragraphs 15, 30-31, 42-43; Figs. 2-3.

Lastly, with regard to the aspect of the invention set forth in independent claim 33, discussions of the recited features of claim 33 can be found at least in the below cited locations of the specification and drawings. An exemplary embodiment of claim 33 provides a computer program embodied on a computer readable medium (*e.g.*, for managing clinical study (CS) information (*e.g.*, 92). *See, e.g., id.* at paragraphs 15, 18, 28-32; Figs. 2-3. The computer readable medium includes a code segment that receives

CS information (*e.g.*, 92) relating to at least one patient (*e.g.*, 112) involved in a clinical study (*e.g.*, 94) through a user selected template displayed on a client system (*e.g.*, 14), wherein the user selected template is selected from a plurality of templates stored in a centralized database (*e.g.*, 20), each of the plurality of templates configured to correspond to specific clinical studies (*e.g.*, 94). *See, e.g., id.* at paragraphs 15, 18, 26, 28-32, 35-37; Figs. 1-3. The computer readable medium further includes a code segment that maintains a database (*e.g.*, 20) by adding, deleting and updating CS information (*e.g.*, 92), tracks (*e.g.*, via tracking component 66) CS information, and provides (*e.g.*, step 280, via providing component 90) CS information (*e.g.*, 92) in response to an inquiry (*e.g.*, request received at step 252) by a user. *See, e.g., id.* at paragraphs 15, 18, 26, 28-32, 35-37; Figs. 1-3. Finally, the computer readable medium includes a code segment (*e.g.*, retrieving component 80) configured to transmit to the client system (*e.g.*, 14) at least one report summarizing CS information (*e.g.*, 92) and findings relating to at least one of a clinical study (*e.g.*, 94) and a patient (*e.g.*, 112) involved in a clinical study (*e.g.*, 92). *See, e.g., id.* at paragraphs 15, 28-32, 42-43; Figs. 2-4.

Aspects of the claimed techniques provide a standardized format in which clinical research data may be acquired and stored, thus providing clinical research entities a system and method for improved management of clinical research data. The foregoing techniques offer various advantages compared to traditional methods and systems for maintaining clinical research data, such as in paper form. As such, clinical study data may be more easily viewed and analyzed by appropriate persons, i.e., physicians and medical personnel, thus facilitating the accuracy of medical diagnoses, optimizing the use of medical equipment in the diagnoses and treatment of patients, and aiding in the production of next generation medical equipment and the optimization of clinical applications.

6. **GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

First Ground of Rejection for Review on Appeal:

Whether the Examiner has satisfied the burden of establishing a *prima facie* case that claims 1-16 are indefinite under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which Appellants regard as the invention.

Second Ground of Rejection for Review on Appeal:

Whether the Examiner has satisfied the burden of establishing a *prima facie* case that claims 1-9, 13-25, and 29-38 are anticipated under 35 U.S.C. § 102(b) by Brown, U.S. Patent No. 6,196,970 (hereinafter "Brown").[1]

Third Ground of Rejection for Review on Appeal:

Whether the Examiner has satisfied the burden of establishing a *prima facie* case that claims 4-5, 15, 20-21, 31, and 34-35 are obvious under 35 U.S.C. § 103(a) over Brown in view of Goldwasser, U.S. Patent No. 4,737,921 (hereinafter "Goldwasser").

Fourth Ground of Rejection for Review on Appeal:

Whether the Examiner has satisfied the burden of establishing a *prima facie* case that claims 10-11, 26-27, and 39-40 are obvious under 35 U.S.C. § 103(a) over Brown in view of Rice et al., U.S. Pre-Grant Publication No. 2002/0042723 A1 (hereinafter "Rice").

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[1] It should be noted that the Examiner only stated that claims 1-3, 6-9, 13-14, 16-19, 22-25, 29-30, 32-33, and 36-38 were anticipated by Brown in the "Section 102" portion of the Final Office Action. *See* Final Office Action, page 4. However, in the "Section 103" portion of the Final Office Action, the Examiner stated that claims 4-5, 15, 20-21, 31, 34-35 were rejected under Section 103 as being obvious over Brown in view of Goldwasser or, *alternatively*, under Section 102 in view of Brown. *See id.* at page 15. Thus, for the purposes of this appeal, we have interpreted the Examiner's statements to mean that each of claims 1-9, 13-25, and 29-38 are anticipated by Brown.

Fifth Ground of Rejection for Review on Appeal:

Whether the Examiner has satisfied the burden of establishing a *prima facie* case that claims 12 and 28 are obvious under 35 U.S.C. § 103(a) over Brown in view of Applicant Admitted Prior Art (hereinafter "AAPA").

7. ARGUMENT

As discussed in detail below, the Examiner has improperly rejected the pending claims. Further, the Examiner has misapplied long-standing and binding legal precedents and principles in rejecting the claims under Sections 102, 103, and 112. Accordingly, Appellants respectfully request full and favorable consideration by the Board, as Appellants strongly believe that claims 1-40 are currently in condition for allowance.

A. First Ground of Rejection:

The Examiner rejected claims 1-16 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Appellants regard as the invention. Appellants respectfully traverse this rejection.

As an initial matter, Appellants note that the Examiner set forth three separate grounds for rejecting claims 1-16 under Section 112, second paragraph, in the Final Office Action. *See* Final Office Action, pages 2-4. The grounds of rejection are summarized below:

1. The Examiner stated that it is unclear as to whether the term "using," as recited in claim 1, refers to using a "method" or "clinical research entity."

2. The Examiner stated that the recitation of the term "information" in claim 14 lacks a nexus with the remainder of the claim.

3. The Examiner stated that the recitation of the term "tracking" in claims 1 and 14 could not be interpreted in light of the specification and that in

> setting forth the present rejections, the Examiner interpreted the "tracking" of data to be equivalent to "updating" data.
>
> *See id.*

As stated above, claims 1 and 14 were amended by the previously filed Response to the Final Office Action to address the Section 112, second paragraph rejections. *See generally*, Response to Final Office Action filed January 26, 2008, pages 2 and 6. In the subsequently mailed Advisory Action, the Examiner indicated that these amendments were entered and that the first and second grounds of rejection discussed above have been overcome. *See* Advisory Action, pages 1-2. As such, it appears that *only* the third ground of rejection regarding the recited term "tracking" is still currently outstanding. Accordingly, Appellants have addressed only this remaining ground of rejection in the arguments below.

1. **Judicial precedent has clearly established a legal standard for a rejection under Section 112, second paragraph, on grounds of indefiniteness.**

As the Board is well aware, the Examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. *See* M.P.E.P. § 2173.02. Although the Examiner may take exception to the terms used in the claims, the patentee may be his own lexicographer. *Ellipse Corp. v. Ford Motor Co.*, 171 U.S.P.Q. 513 (7th Cir. 1971), *aff'd.* 613 F.2d 775 (7th Cir. 1979), *cert. denied*, 446 U.S. 939 (1980). Appellants may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought. *See* M.P.E.P. §§ 2173.01 and 2173.05; *In re Swinehart*, 439 F.2d 10, 160 U.S.P.Q. 226, (CCPA 1971). It is also axiomatic that breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 U.S.P.Q 597 (CCPA 1971).

The essential inquiry pertaining to the definiteness requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. *See* M.P.E.P. § 2173.02. As set forth in Section 2173 of the Manual of Patent Examining Procedure, definiteness of claim language must be analyzed, not in a vacuum, but in light of:

(A) The content of the particular application disclosure;

(B) The teachings of the prior art; and

(C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the Examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent. *See Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 U.S.P.Q.2d 1279, 1283 (Fed. Cir. 2000). Only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite. *See Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366, 71 U.S.P.Q.2d 1081, 1089 (Fed. Cir. 2004). Accordingly, a claim term that is not used or defined in the specification is not indefinite if the meaning of the claim term is discernible. *See Bancorp Services, L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1372, 69 U.S.P.Q.2d 1996, 1999-2000 (Fed. Cir. 2004).

2. **One of ordinary skill in the art will readily recognized that "tracking" and "updating" data, as recited by independent claims 1 and 14, are two different actions in the context of the present application and, therefore, the Examiner's assertion that the term "tracking" is indefinite under 35 U.S.C. § 112, second paragraph, is erroneous.**

Appellants respectfully disagree with the Examiner's interpretation of the term "tracking" as being equated with the term "updating." As the Board will appreciate, it is well established case law that during patent examination, the pending claims must be given an interpretation that is *reasonable* and *consistent* with the specification. *See In re Prater*, 162 U.S.P.Q. 541, 550-51 (C.C.P.A. 1969); *In re Morris*, 44 U.S.P.Q.2d 1023, 1027-28 (Fed. Cir. 1997); see also M.P.E.P. § 2111 (describing the standards for claim interpretation during prosecution). With the foregoing in mind, Appellants respectfully submit that contrary to the Examiner's assertions, the "tracking" of CS information, as recited by independent claims 1 and 14 is clearly defined and supported at least by paragraph 28 of the specification.

In particular, paragraph 28 discloses that certain embodiments of the present invention may include a tracking component 66 which *tracks and cross-references data*. *See* Application, paragraph 28. In the Advisory Action mailed February 11, 2008, the Examiner appeared to take the position that because the tracking component 66 is further described in the specification as also being capable modifying existing data in *addition* to tracking and cross-referencing data, that these actions are all somehow the same. *See* Advisory Action, page 3. Appellants respectfully disagree and submit that while the aforesaid actions may be performed in conjunction with one another to achieve a common goal or objective, they are, nevertheless, still *separate and distinct* actions. Appellants further submit that the tracking component 66 need not necessary be limited *only* to performing the tracking of data in the centralized database 20.

As those skilled in the art will recognize, in managing a database, such as the recited "centralized database" of independent claim 1, it may be necessary to track and

cross-reference changes in the data in order to provide a user with the most current data or information (e.g., updated data) or, in some cases, to provide information as to how a data point of interest has progressed or changed over time. Thus, while the tracking component 66 *may* also be capable of performing updates to the database, the data to be updated must *first* identified by "tracking" and cross-referencing the data with newly acquired data via the tracking component 66 in order to determine whether such updates are even required. Accordingly, Appellants submit that while *tracking* data may be a prerequisite to *updating* data, the two steps are still distinct, and thus not identical, as alleged by the Examiner.

Moreover, Appellants note that this point is further evidenced by the plain language of the claim in question. For example, independent claim 1 *clearly* recites "tracking" CS information and "updating" the centralized database as being *two* separate steps of the recited method. Thus, it is clear that one skilled in the art *would not* interpret these steps as being identical. Accordingly, Appellants submit that given the plain language of the pending claims, one of ordinary skill in the art would *not* interpret "tracking," as recited by independent claims 1 and 14, to be analogous to "updating" and, therefore, the Examiner's assertion that the term "tracking" is indefinite under Section 112, second paragraph, cannot be supported.

3. **Request Reversal of the Rejection**

In view of the reasons set forth above, Appellants respectfully request that the Board reverse the rejection of claims 1-16 under 35 U.S.C. § 112, second paragraph, and instruct the Examiner to allow these claims.

B. **Second Ground of Rejection:**

The Examiner rejected claims 1-9, 13-25, and 29-38 under 35 U.S.C. § 102(b) as being anticipated by Brown. Appellants respectfully traverse this rejection. Further, because the Examiner rejected each of independent claims 1, 14, 17, 30, and 33 on this

basis, these independent claims will be discussed in detail below. In summary, the Examiner's rejection of independent claims 1, 14, 17, 30, and 33 is believed to be improper for at least three reasons:

(1) Brown fails to disclose a "template," much less a "plurality of templates";

(2) Brown fails to disclose that a "template" is selected from a "plurality of templates"; and

(3) Brown fails to disclose that each of a "plurality of templates" corresponds to a specific clinical study.

These above-listed features are generally recited by each of independent claims 1, 14, 17, 30, and 33. The deficiencies of Brown with regard to these above-listed features will be discussed in further detail below.

1. **Judicial precedent has clearly established a legal standard for a *prima face* anticipation rejection under Section 102.**

Anticipation under Section 102 can be found only if a single reference shows exactly what is claimed. *See Titanium Metals Corp. v. Banner*, 227 U.S.P.Q. 773 (Fed. Cir.1985). For a prior art reference to anticipate under Section 102, every element of the claimed invention must be identically shown in a single reference. *See In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir.1990). That is, the prior art reference must show the *identical invention "in as complete detail as contained in the ... claim"* to support a *prima facie* case of anticipation. *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q. 2d 1913, 1920 (Fed. Cir. 1989) (emphasis added). Thus, for anticipation, the cited reference must not only disclose all of the recited features but must also disclose the *part-to-part relationships* between these features. *See Lindermann Maschinenfabrik GMBH v. American Hoist & Derrick*, 221 U.S.P.Q. 481, 486 (Fed. Cir.1984). Accordingly, Appellants need only point to a single element or claimed relationship not found in the cited reference to demonstrate that the cited reference fails to anticipate the claimed subject matter.

Moreover, it is well-established case law that during patent examination, the pending claims must be given an interpretation that is *reasonable* and *consistent* with the specification. *See In re Prater*, 162 U.S.P.Q. 541, 550-51 (C.C.P.A. 1969); *In re Morris*, 44 U.S.P.Q.2d 1023, 1027-28 (Fed. Cir. 1997); see also M.P.E.P. §2111 (describing the standards for claim interpretation during prosecution). Indeed, the *specification* is "the primary basis for construing the claims." *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005). (Emphasis added). It is usually dispositive. *See id.* Interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. *See In re Cortright*, 49 U.S.P.Q.2d 1464, 1468 (Fed. Cir. 1999); *see also* M.P.E.P. §2111. That is, recitations of a claim must be read as they would be interpreted by those of ordinary skill in the art. *See Rexnord Corp. v. Laliram Corp.*, 60 U.S.P.Q.2d 1851, 1854 (Fed. Cir. 2001); *see also* M.P.E.P. § 2111.01. In summary, an Examiner, during prosecution, must interpret a claim recitation as one of ordinary skill in the art would reasonably interpret the claim in view of the specification. *See In re American Academy of Science Tech Center,* 70 U.S.P.Q.2d 1827 (Fed. Cir. 2004). With the foregoing legal precedent in mind, Appellants address the Section 102 rejection below.

2. **The Examiner's rejection under 35 U.S.C. § 102 is improper because Brown fails to disclose a template, and thus fails to disclose a plurality of templates, as generally recited by each of independent claims 1, 14, 17, 30, and 33.**

Appellants note that each of independent claims 1, 14, 17, 30, and 33 generally recites the use of a user-selected template. For instance, independent claims 1, 17, and 33 each recite "a *user-selected template* … selected from a *plurality of templates* stored in a centralized database." (Emphasis added.) Similarly, independent claims 14 and 30 each recite "a *template selected by a user* from a *plurality of templates* stored in a centralized database." (Emphasis added.) Appellants respectfully submit that Brown fails to disclose the recited user-selected template.

With regard to embodiments of the present invention, a template selected by a user from the plurality of templates may be used to collect clinical study (CS) information during the course of a clinical study. Each of the plurality of templates may contain data fields by which a patient or a physician may enter data, such as data related to a patient's name, sex, medical history, weight, height, age, etc. *See* Application, paragraph 15. A graphical representation of the recited "template" is illustrated in Fig. 3 of the present application. *See id.* at Fig. 3. Thus, the recited plurality of templates provides a *standardized* format for storing and maintaining CS information in a digital medium. *See id.* at paragraph 4. As described in the background section of the present application, such information and data has historically been maintained in paper form. *See id.* at paragraphs 2-3. Thus, managing the information so that it may be viewed in a standardized format is difficult, time consuming, and costly. *See id.* Accordingly, the use of a standardized set of templates provided by embodiments of the present invention is directed towards overcoming the drawbacks of the known prior art methods and systems for managing CS information and data. *See id.*

Throughout the prosecution of the present application, the Examiner repeatedly maintained the erroneous assumption that the recited "plurality of templates" is analogous to "a protocol," as disclosed by Brown. *See* Office Action mailed June 21, 2007, pages 2-3; *see also* Final Office Action mailed November 28, 2007, page 5. In particular, the Examiner stated that "information concerning the type of data to be collected and the protocol collectively are considered to be 'a template.'" *Id.* Appellants respectfully disagree with the Examiner's interpretation. As noted repeatedly by Appellants, the terms "template" and "protocol" are simply *not* comparable. *See* Response to Office Action mailed June 21, 2007, page 20; Response to Final Office Action mailed November 28, 2007, page 21. For instance, as noted by Appellants in the previously filed Response to the Final Office Action, *The Random House Dictionary of the English Language, Unabridged*, defines the term "protocol," when used in a medical context, as being "[a] plan for carrying out a scientific study or a patient's treatment regimen." *See* Response to

Final Office Action mailed November 28, 2007, page 21; *see also* Definition 6 of "protocol." *Random House Dictionary of the English Language, Unabridged*, 2nd ed., page 1555 (1987). A copy of this dictionary definition is provided as Exhibit A in the Appendix of Evidence attached hereto.

With the foregoing in mind, Appellants believe a brief summary of the teachings of Brown is in order. As noted in the background section of Brown, the invention set forth therein is meant to address problems relating to the conventional use of testing protocols in clinical studies, such as a Food and Drug Administration ("FDA") drug clinical trial. *See* Brown, col. 1, lines 5-43. According to Brown, during the course of an FDA drug trial, the sponsor of an experimental drug first submits an application and a *testing protocol* to the FDA. *See id.* at col. 1, lines 44-46. In an initial phase of testing, such as Phase I of an FDA clinical trial, the testing protocol may include guidelines relating to the number of volunteers and detailing the specific factors are to be studied or monitored (*e.g.*, drug dosage effects and drug metabolism characteristics). *See id.* col. 1, lines 48-52. Thereafter, in Phase II (e.g., following successful completion of Phase I testing), the testing protocol may be further expanded to include studying the effectiveness of the drug, adverse reactions, etc., as well as increasing the number of test subjects. *See id.* col. 1, lines 58-65. Indeed, the use of the term "protocol," by Brown *clearly* refers to the particular plan for carrying out an FDA drug study. Further, Appellants submit that this appears to be in accordance with the general well-known definition of the term "protocol," as discussed above and as would be recognized by persons skilled in the art.

Brown notes several drawbacks, however, with regard to the known conventional methods for carrying out FDA drug testing. In particular, once the initial drug testing protocol is submitted, it is difficult to modify the protocol during the course of the study. For instance, Brown discloses that one problem with the use of conventional testing protocols is the inability to evaluate and standardize self-assessments from participating

patients. *See id.* col. 2, lines 32-44. Thus, because it is both costly and impractical to keep a sufficient staff of medical experts on hand to interview or solicit feedback from each and every test subject, the study may rely heavily on self-assessments reported by the test subjects, which may often include subjective or "fuzzy" answers as to physical state and/or mood that are difficult or even impossible to analyze objectively. *See id.* A further problem noted by Brown is the inability to modify a testing protocol in real time. *See id.* col. 2, lines 45-67. That is, although it may be desirable to alter an existing testing protocol based on data analyzed during the course of a clinical study, the clinical study data may not aggregated or entered until near the conclusion of the trial, thus making it impossible for a researcher or medical professional to effectively modify or adjust the protocol while the study is in process. *See id.*

Accordingly, Brown discloses a system and method designed to more effectively allow modification of testing protocols based on received data in order to address the aforementioned drawbacks. In particular, Brown discloses that each participating subject is provided a "client device" on which the research protocol is installed. *See id.* col. 4, lines 1-6. Based on the particular protocol on the client device, a test subject may respond to questions, such as whether symptoms were relieved after ingesting the drug, as well as other general questions directed towards the test subject's physical and mental well-being. *See id.* col. 4, lines 6-9. Depending on the nature of the drug being tested, the client device, operating under the testing protocol, may also instruct the test subject to enter data, such as from a glucose monitor (e.g., the drug may be designed to relieve diabetic symptoms), which although not explicitly disclosed by Brown, is presumably provided to the test subject along with the client device. *See id.* col. 4, lines 9-12. Still further, Brown discloses that as part of the patient self-assessment, the protocol may present narrowly structured questions as well as suggested answers, and that in the event of ambiguous or incomprehensible answers, the testing protocol may include formulating additional questions in order to more effectively direct the patient's response towards a more objectively analyzable answer. *See id.* col. 4, lines 12-19. Additionally, the testing

protocol may also include providing a restricted set of possible answers (*e.g.*, multiple choice, true/false). *See id.* Because it is often difficult to draw sound scientific conclusions from non-objective data, these techniques set forth in Brown are designed reduce or eliminate the subjective nature of answers that are commonly provided by patients participating in such studies.

Brown further discloses that the self-assessment response provided by the patient through the client device is relayed to a server by a communication uplink, such that the data may be received and aggregated with data received from other test subjects in real time and statistically analyzed by parameters, which may be set by the testing protocol. *See id.* As such, medical and research personnel monitoring the drug study may be able to modify the protocol in response to the received data. *See id.* col. 4, lines 29-31. Brown discloses that modifying the protocol may include using parameters identified in the received data to better identify subjects responding positively to treatment, identifying subgroups among the testing population, or initiating additional self-assessment inquiries based on the analyzed data. *See id.* col. 4, lines 31-39. In other words, Brown is directed towards a system and method for *modifying a protocol*, which appears to be defined as a plan for carrying out an FDA experimental drug study.

Brown also explicitly states that the protocol installed on the client device is an "intelligent message, [which] acts in place of a researcher, investigator, clinician or other medical expert." *Id.* col. 4, lines 65-67. (Emphasis added.) Thus, it would appear that Brown intends for the protocol installed on the client devices to act as a thorough but automated form of soliciting feedback from each test subject, distributing guidelines or instructional messages for operating medical research equipment (*e.g.*, such as the above discussed glucose monitor), thereby reducing the need for constant supervision and assistance from medical personnel. This is in accordance with solving the above discussed issues regarding the high costs and impracticality of keeping a full staff of

medical experts on hand to interview or solicit feedback day after day from what may be hundreds or even thousands of test subjects participating in a single drug trial study.

In stark contrast, the term "template," as recited by each of the independent claims, is focused on a device or interface containing "fields that prompt a user to enter specific CS (clinical study) data 92 or to display specific CS data 92." Application, paragraph 35. The use of a "template" allows for the organization (e.g., acquisition and storage) of the CS data in a *standardized format*, thereby facilitating subsequent viewing, retrieval, and analysis by medical experts. *See id.* at paragraph 4. For example, such fields may include a patient's name, sex, medical history, weight, height, age, etc. *See id.* at paragraph 15; Fig. 3. Indeed, in the present context, a standardized template is clearly defined as having a set of fields allowing users to enter or view specific CS data. It is not, as the Examiner has alleged, analogous to a testing protocol.

In response to Appellants' arguments in the previously filed Response, the Examiner provided in the Final Office Action a dictionary definition of the term "template" as follows:

> Webster's II Dictionary, Second Edition defines "template" as "a gauge or pattern… used in making or copying something accurately."
>
> Final Office Action, page 22.

Moreover, to the extent that the Examiner relied on this dictionary definition, the Examiner further stated that:

> …it is noted that the features upon which [A]pplicant[s] rel[y] (i.e., a set of fields allowing "a user to enter specific CS (clinical study) data 92 or to display specific CS data 92 for a user to view and analyze") are not recited in the rejected claim(s). Although the claims are

> interpreted in light of the specification, limitations from the specifications are not read into the claims.
>
> Assuming *arguendo* this limitation flows inherently therefrom, Brown teaches displaying a portion of the protocol to the research subject to extract a response via an input (Figure 2a level 206-207). Brown further teaches that a protocol can include questions for the subject (Abstract).
>
> *Id.* at pages 23-24.

Based on these comments, it appears that the Examiner has flatly refused to consider Appellants' previously submitted arguments on the grounds that the *dictionary* definition of "templates" does not explicitly disclose "a set of fields." Further, in the Advisory Action mailed on February 11, 2008, the Examiner asserted that paragraph 35 of the present application fails to define a "template," but merely discusses alternative embodiments and non-commital features. *See* Advisory Action mailed February 11, 2008, page 4. Appellants respectfully disagree with this line of reasoning.

In particular, Appellants note that when a claim recites a term that is not commonly known or used in the art, such a term is to be interpreted in view of the specification and in manner that is *consistent* with the interpretation that a person of ordinary skill in the art would reach. *See In re Prater*, 415 F.2d 1393, 1404-05, 162 U.S.P.Q. 541, 550-51 (C.C.P.A. 1969) (emphasis added); *see also In re Morris,* 127 F.3d 1048, 1054-55, 44 U.S.P.Q.2d 1023, 1027-28 (Fed. Cir. 1997); *see also* M.P.E.P. §§ 608.01(o) and 2111; *see also In re Cortright*, 165 F.3d 1353, 1359, 49 U.S.P.Q.2d 1464, 1468 (Fed. Cir. 1999); M.P.E.P. § 2111. Further, while Appellants certainly appreciate the difficulty faced by the Examiner in interpreting the claims in view of the specification without improperly importing limitations from the specification into the claims, Appellants respectfully note that the Federal Circuit, sitting *en banc*, recently provided a summary and additional guidance regarding the proper interpretation of claims in view of the specification. *See Phillips v. AWH Corp.*, 75 U.S.P.Q.2d 1321 (Fed. Cir. 2005) (*en*

banc). In *Phillips*, the Federal Circuit again emphasized the primacy of the specification in claim interpretation. Particularly, the *Phillips* court noted that the specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; *it is the single best guide to the meaning of a disputed term*." *Phillips*, 75 U.S.P.Q.2d at 1327 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)) (Emphasis added.) Moreover, the court also noted that:

> Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language *and most naturally aligns with the patent's description of the invention* will be, in the end, the correct construction.
>
> *Phillips*, 75 U.S.P.Q.2d at 1328-29 (Emphasis added).

In other words, the case law clearly states that it is the ***specification*** itself is the *best* resource for interpreting a disputed claim term.

With the above controlling case law in mind, Appellants submit to the Board that the Examiner's continued reliance on a mere dictionary reference and blatant refusal to consider the specification of the present application in interpreting the term "user-selected template," as generally recited by each of the pending independent claims, is not only in direct contrast with legal precedent established by both the former C.C.P.A. and the Federal Circuit, but also inconsistent with the reading one skilled in the art would reach when interpreting the claims. Indeed, as discussed above, the recited "template" is *clearly* described in the Application as being directed towards a standardized format having a set of fields for entering/storing CS data, and designed to replace traditional non-uniform paper-based systems for recording CS data. *See* Application, paragraphs 2, 35.

Further, Appellants respectfully submit that the mere fact that the protocol of Brown might include submitting questions to a patient as part of a drug study would clearly not merit an interpretation by one of ordinary skill in the art that a "protocol" is analogous to the recited "template." Instead, to the extent that the recited "templates" of the pending claims have any relation whatsoever to "protocols," it is, as stated in the present application, that the CS information entered into the *user template* may be used to gather *protocols* for operating medical devices. *See id.* at paragraphs 27, 34. However, one skilled in the art will clearly recognize that the recited user templates themselves are *distinct* and thus, *not analogous* to the protocols which may be gathered or developed using the CS information stored in the templates. Additionally, Appellants note that nothing in Brown appears to teach or suggest that a *protocol* is developed as a result of clinical information entered through a *template* or that a "protocol" allows user entry of CS data via a set of fields or the display and retrieval of such data. Rather, it appears that the Examiner has made the illogical leap that a standardized template exists in Brown simply because Brown appears to suggest that the solicitation of answers from patients may be *part* of a drug testing *protocol*.

Still further, Appellants respectfully note that the recited templates, as discussed above, are directed towards providing a *standardized* format for receiving, storing, viewing, and analyzing CS data. In other words, to streamline the management of CS data, a *standard* form is used to collect the data. This ensures uniformity amongst all the data collected in a particular study by using the *same* template throughout the course of a study. In contrast, Appellants submit that there is nothing *standardized* about the system and method disclosed in Brown. As discussed above, Brown is teaches a method and system directed towards *continuously modifying* a testing protocol based upon the analysis of clinical study data. *See* Brown, col. 2, lines 58-67 (noting that the inability to modify a protocol is a problem in the prior art); col. 3, lines 41-63; col. 7, lines 1-6. Therefore, it would seem that Brown intends for the protocol to *change* throughout the course of the study in accordance with patient feedback. Indeed, this appears to be in

direct contrast and wholly inconsistent with the manner in which a "template" if defined in the present Application and recited in each of the presently pending claims.

Accordingly, in view of the numerous reasons set forth above, Appellants respectfully submit to the Board that when considering the terms "template" and "protocol" in view of their respective specifications, a person skilled in the art *would not* and *could not* reasonably conclude that a protocol is analogous to the recited "template" of independent claims 1, 14, 17, 30, and 33. As such, Appellants assert that Brown does *not* teach or suggest a template, much less a *plurality of templates*, as recited by each of these independent claims.

3. **Even hypothetically assuming that the protocol disclosed by Brown could be considered the recited template, the Examiner's rejection under 35 U.S.C. § 102 is still improper because; Brown further fails to disclose that the protocol is selected from a plurality of protocols, as generally recited for the templates in each of independent claims 1, 14, 17, 30, and 33.**

Appellants note that each of the independent claims pending in the present application generally recites the selection of a template (e.g., user selected template) from a plurality of templates stored in a centralized database. As discussed above, the Examiner's rejection asserts that a "protocol," as disclosed by Brown, is analogous to a "template," as recited by each of independent claims 1, 14, 17, 30, and 33. For at least the reasons set forth above, this analogy is believed to be clearly erroneous. That is, because Brown fails to even disclose a single template, Appellants submit that Brown cannot possibly disclose *selecting a template* from a *plurality of templates*, as recited by each the presently pending independent claims.

However, even assuming, *arguendo*, that a "protocol" *could* somehow be construed as being analogous to the recited "template," Appellants submit that the Brown *still* fails to disclose that the protocol is selected from a *plurality of protocols* (templates).

As discussed above, Brown discloses that an initial testing protocol is generally formulated and submitted to the FDA prior to receiving approval for testing a new drug. *See id.* at col. 1, lines 44-46. Further, the protocol is clearly laid out in Brown as being a plan or set of rules and guidelines for carrying out a scientific study and, in the context of clinical drug studies, may relate to guidelines for determining the number of volunteers, what factors are to be studied (e.g., drug dosage effects and drug metabolism characteristics), guidelines for studying the effectiveness of the drug, monitoring of adverse reactions, etc. *See id.* col. 1, lines 48-61. The protocol may further include guidelines for expanding the number of test subjects during later phases of the study. *See id.* col. 1, lines 61-65.

To improve conventional protocol-based clinical testing methods, Brown discloses a system and method that expedites the collection and analysis of drug testing data from the test subjects. As such, research experts monitoring the study may be better equipped to identify certain data points or trends for the purposes of modifying the testing protocol to optimize the collection of reliable data in subsequent stages of the study. However, Appellants submit that nothing in Brown suggests that the clinical researches are selecting a protocol from a *plurality* of protocols. In fact, as will be appreciated by those skilled in the art, it would be it would be detrimental if different testing protocols were used simultaneously within the same study, as the reliability of the acquired data would be inconsistent and thus compromised.

In responding to Appellants' previous arguments with regard to this claimed feature, the Examiner stated that:

> Brown teaches that:
>
> (a) the server device records the information concerning the type of data to be collected and protocol in the database (Figure 2a label 204);

> (b) the server device records the *modified* protocol in the database (Figure 2b label 218);
>
> (c) steps (a)-(b) are repeated (Figure 2b label 221), thereby creating a plurality of protocols stored in the database (It is noted that nowhere does Brown teach deleting, or otherwise expunging or purging, protocol from the database);
>
> (d) the medical research expert either leave the protocol unchanged or modify the protocol as necessary (It is noted that a protocol is "selected" by the medical research expert for implementation) (column 7 line 3-5).
>
> According to the teachings of Brown, a medical research expert is presented with the choice to either modify the protocol or leave the protocol as-is. When steps (a)-(b)
> are repeated, the database stores therein a plurality of protocols as the results of the medical research expert modifying the protocol during each repetition of the loop.
>
> Examiner submits that when the medical research expert leaves a protocol as-is, the medical research expert is in effect "selecting" to implement the instant protocol over the plurality of protocols implemented in previous loops.
>
> Final Office Action, pages 21-22. (Emphasis added.)

In other words, it appears that the Examiner is suggesting that because Brown does not *explicitly* disclose that modifying the protocol includes removing or expunging the *previous* "versions" of the protocol, these "out-dated" protocols must remain somewhere in the database, thus constituting a plurality of protocols. Appellants respectfully disagree with the Examiner's interpretation.

Although Appellants acknowledge that Brown does not *explicitly* disclose that "old versions" of the testing protocol are discarded from the server, Appellants submit that the Examiner's interpretation of Brown in this regard is in clear contradiction with

the interpretation one of ordinary skill in the art would reach. First, Appellants submit that the plain meaning of the terms "modifying or "changing" a protocol imply that a researcher is making a change or modification to an *existing* protocol. Appellants further submit that one of ordinary skill in the art would not interpret "modifying a protocol" to mean that a researcher creates a copy of the original protocol (which is identical to the original protocol), implements the desired changes in the copy of the protocol (creating the modified protocol), and then saves or otherwise stores the "modified" protocol *alongside* the "original protocol" in a server.

In accordance with the system and method disclosed by Brown, it is desirable to update (*e.g.*, modify) the protocol based on acquired patient data. For instance, Brown states that one drawback of the prior art is that "researches are unable to modify a clinical protocol while in progress" and that if such a solution is provided, "it is believed that morbidity and mortality associated with evaluation of new drugs could be *substantially* reduced if researches could respond during the research such to halt the clinical trial or adjust the drug dosage." Brown, col. 2, lines 58-67. Thus, Brown clearly sets forth that a researcher would *always* want to use the *most recent* version of the protocol in order to acquire the most reliable data while reducing possible harm to the test subjects. Accordingly, Appellants submit that Brown does not explicitly disclose expunging the old protocol versions because under the system and method of Brown, one of ordinary skill in the art would infer that these old and out-of-date protocols would *never* be used again due to morbidity and mortality concerns, as discussed above.

To provide a hypothetical example, suppose a researcher desires to conduct a study regarding a drug for reducing the occurrence of facial acne in young adults and submits an application and testing protocol to the FDA, in which the submitted protocol initially calls for an equal sample of male and female test subjects. Let us suppose that an analysis of the research data from a first testing phase indicates that the drug is highly effective in male test subjects for eliminating acne, but causes severe skin reactions and

rashes in female patients while doing little to combat acne in the female patients. Accordingly, the research experts monitoring the study may find it pertinent to modify the existing testing protocol, for example, to exclude future data received from the already participating female subjects in order to prevent skewing of the test results demonstrating the effectiveness of the drug in male subjects and/or to exclude selection of additional female test subjects when selecting additional test subjects for subsequent FDA testing phases, as it is now known that females may experience sever and undesirable side-effects when taking the subject drug. Accordingly, Appellants submit that it would neither be logical nor efficient to keep the original protocol because upon realization that female test subjects should not be included in future testing due to health concerns as well as the ineffectiveness of the drug in female test subjects, there would be never be a need to revert to the original protocol.

Appellants note that the Examiner's only line of reasoning in asserting Brown teaches the selection of a protocol from a *plurality* of protocols appears to be based on the contention that each *modification* of a protocol constitutes a *new* separate protocol. However, in view of the hypothetical example provided above, such an interpretation is clearly erroneous. Moreover, Appellants note that the Examiner appears to admit in the Advisory Action that a protocol could be constant. Specifically, the Examiner stated "[b]ased on the evidence presented above, Examiner submits that the protocol of Brown may be constant." Advisory Action, page 6. However, if the Examiner chooses to interpret a protocol as being *constant*, then such an interpretation would preclude the Examiner's logic that a *changing* protocol constitutes a plurality of protocols/templates. Indeed, this statement appears to be in direct contradiction with the Examiner's previous arguments and, in fact, would seem to imply that in certain instances Brown *does not* disclose a plurality of protocols.

Therefore, in view of the Examiner's own contradicting statements, Appellants submit that Brown does not disclose a plurality of protocols from which a single protocol

is selected. That is, one of ordinary skill in the art would readily acknowledge that the passages of Brown which disclose "modifying" or "changing" a protocol are directed towards making changes in an *existing* protocol, *without* instantiating a *new* protocol each time a modification is performed. Accordingly, even assuming hypothetically that the recited "templates" could be analogous with a "protocol," Appellants believe the Examiner's assertions that Brown discloses *selecting a protocol* from a *plurality of protocols* cannot be supported by the plain teachings of the reference itself.

4. **Even hypothetically assuming that the Brown discloses a plurality of protocols, the Examiner's rejection under 35 U.S.C. § 102 is still improper because, Brown further fails to disclose that each of the plurality of protocols corresponds to specific clinical studies, as generally recited by each of independent claims 1, 14, 17, 30, and 33.**

Appellants further note that each of independent claims 1, 14, 17, 30, and 33 further recites that each of a "plurality of templates" is configured to correspond to "specific clinical studies." Appellants submit that this recited feature is also not present in Brown.

As described above, a drawback in prior art clinical study (CS) data management is the lack of a standardized format for maintaining CS data. *See* Application, paragraphs 2-3. Conventional CS data management methods may involve maintaining data in paper form. *See id.* For clinical research entities that conduct multiple clinical studies simultaneously, maintaining CS data in manner wherein it may be effectively utilized by a plurality of people can be both difficult and costly. *See id.* As such, the present application is directed towards providing a standardized format for acquiring and storing CS data, thereby facilitating the viewing and analysis of the data by medical personnel. *See id.* at paragraph 4. Specifically, the present claims are directed towards systems, methods, and computer programs which provide a plurality of standardized templates, each of contains a plurality of fields for receiving CS data. *See id.* at paragraph 35. Moreover, each of the plurality of templates may be associated with a specific clinical

study. *See id.* at paragraph 36. For example, a "generic template" may be used to create a specific template corresponding to a specific clinical study. *See id.* In other words, the present application discloses that in a given plurality of templates, each *respective* template may correspond to a specific *respective* clinical study. Accordingly, embodiments of the present invention are particularly useful in aiding clinical research entities, which may engage in numerous different clinical studies simultaneously, to better maintain CS data and, therefore, improve viewing, analysis, and management of the CS data.

Further, as discussed in detail above, the Examiner's assertion of a "protocol" as being analogous to the recited "template" of independent claims 1, 14, 17, 30, and 33 is erroneous. Therefore, Brown cannot possibly disclose a template, much less a *plurality of templates*, each corresponding *to specific clinical studies*, as recited by the presently pending independent claims. However, even assuming, *arguendo*, that a "protocol" *could* somehow be correlated to the "template," and that Brown could be interpreted as disclosing a "plurality of protocols," Appellants submit that nothing in Brown suggests that each of the "plurality of protocols" correspond to specific clinical studies.

Rather, as discussed above, the Examiner asserted that Brown discloses a plurality of protocols based on the observation that Brown fails to *explicitly* disclose discarding "old versions" of protocols after the protocol is modified in response to the analysis of drug testing data. Assuming momentarily for the sake of argument that the Examiner is correct in his interpretation of the Brown reference and that Brown *does* indeed disclose a plurality of protocols, Appellants note that the plurality of protocols would essentially constitute different "versions" of a drug testing protocol, with newer versions of the protocol being created each time the testing protocol is modified. However, under the Examiner's interpretation, *each* of the plurality of protocols would correspond to the *same* clinical drug test. In other words, even though the original protocol may have been modified to "produce" a new updated protocol (the asserted "plurality of protocols"), both

protocols would still correspond to the *same* clinical study, not specific clinical studies as recited by each of the pending independent claims.

Therefore, even under the assumption that the Examiner's assertion that Brown teaches a "plurality of protocols" is credible, Appellants submit that there is absolutely no indication that each of the plurality of protocols corresponds to different *specific clinical studies*. They would, in fact, correspond to the *same clinical study*.

5. **Request Reversal of the Rejection**

For at least the reasons set forth above, Brown is believed to be clearly deficient with regard to the above-discussed features of independent claims 1, 14, 17, 30, and 33. Therefore, Appellants respectfully submit that independent claims 1, 14, 17, 30, and 33 are clearly allowable under Section 102(b) over Brown. Further, with regard to claims 2-9, 13, 15-16, 18-25, 29, 31-32, and 34-38, Appellants note that each of these claims depends from one of the allowable independent claims 1, 14, 17, 30, or 33. Thus, Appellants further submit that claims 2-9, 13, 15-16, 18-25, 29, 31-32, and 34-38 are also clearly allowable at least by virtue of dependency from an allowable base claim.

Accordingly, Appellants respectfully request that the Board reverse the rejection of claims 1-9, 13-25, and 29-38 under 35 U.S.C. § 102(b) and instruct the Examiner to allow these claims.

C. **Third Ground of Rejection:**

The Examiner rejected claims 4-5, 15, 20-21, 31, and 34-35 as being obvious under 35 U.S.C. § 103(a) over Brown in view of Goldwasser. Appellants respectfully traverse this rejection.

1. **Judicial precedent has clearly established a legal standard for a *prima face* obviousness rejection under Section 103.**

Before continuing, Appellants note that this present ground of rejection, as well as all the subsequent remaining grounds of rejection which are currently being appealed, are based on obviousness under Section 103. Accordingly, the legal guidelines provided in the present discussion regarding the rejection of claims 4-5, 15, 20-21, 31, and 34-35 believed to be equally applicable to the remaining grounds of rejections as well. Therefore, to avoid redundancy, Appellants have not reproduced the following text for each subsequent discussion, but rather respectfully requests that the Board keep in mind these legal guidelines regarding obviousness rejections under Section 103 while considering each of the remaining grounds of rejections in the present Appeal.

As the Board is well aware, it is well established case law that the burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (PTO Bd. App. 1979). To establish a *prima facie* case, the Examiner must show, among other things, that the combination includes *all* of the claimed elements. *Ex parte Clapp*, 227 U.S.P.Q. 972 (B.P.A.I. 1985). (Emphasis added.) Furthermore, in addressing obviousness determinations under 35 U.S.C. § 103, the Supreme Court in *KSR International Co. v. Teleflex Inc.*, No. 04-1350 (April 30, 2007), reaffirmed many of its precedents relating to obviousness including its holding in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). In *KSR*, the Court also reaffirmed that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.* at 14. In this regard, the *KSR* court stated that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does … because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *Id.* at 14-15. In *KSR*, the court noted that the demonstration of a teaching, suggestion, or motivation to

combine provides a "helpful insight" in determining whether claimed subject matter is obvious. *KSR, slip op.* at 14.

Furthermore, the *KSR* court did not diminish the requirement for objective evidence of obviousness. *Id.* at 14 ("To facilitate review, this analysis should be made explicit. See *In re Kahn,* 441 F.3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness"). As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ."); s*ee also, In re Lee,* 61 U.S.P.Q.2d 1430, 1436 (Fed. Cir. 2002) (holding that the factual inquiry whether to combine references must be thorough and searching, and that it must be based on *objective evidence of record*).

2. **The Examiner's rejection under 35 U.S.C. § 103 is improper because Brown and Goldwasser, even in combination, fail to disclose all the recited claim elements, and thus cannot establish a *prima facie* case of obviousness against claims 4-5, 15, 20-21, 31, and 34-35.**

Appellants respectfully note that each of the claims rejected by the Examiner based on the combination of Brown and Goldwasser depends either directly or indirectly from one of the independent claims rejected by the Examiner under Section 102 in view Brown. In particular, Appellants note that claims 4-5 depend from claim 1, claim 15 depends from claim 14, claims 20-21 depend from claim 17, claim 31 depends from claim 30, and claims 34-35 depend from claim 33.

As discussed above, Brown clearly fails to disclose several of the features recited by each of independent claims 1, 14, 17, 30, and 33. Furthermore, Appellants submit that Goldwasser fails to obviate the deficiencies of Brown. Indeed, it appears that the Examiner merely relied upon Goldwasser for the teaching of certain medical

devices, including a computed tomography device, a radiography device, and an ultrasound imaging device. Although Appellants do not necessarily concede that Goldwasser discloses these elements, Appellants respectfully submit that these elements alone do not overcome the deficiencies of Brown. As such, dependent claims 4-5, 15, 20-21, 31, and 34-35 are believed to be allowable at least by virtue of their dependencies from an allowable base claim.

3. **Request Reversal of the Rejection**

In view of the reasons set forth above, Appellants respectfully request that the Board reverse the rejection of claims 4-5, 15, 20-21, 31, and 34-35 under 35 U.S.C. § 103(a) and instruct the Examiner to allow these claims.

D. **Fourth Ground of Rejection:**

Whether the Examiner has satisfied the burden of establishing a *prima facie* case that claims 10-11, 26-27, and 39-40 are obvious under 35 U.S.C. § 103(a) over Brown in view of Rice. Appellants respectfully traverse this rejection.

1. **The Examiner's rejection under 35 U.S.C. § 103 is improper because Brown and Rice, even in combination, fail to disclose all the recited claim elements, and thus cannot establish a *prima facie* case of obviousness against claims 10-11, 26-27, and 39-40.**

Appellants respectfully note that each of the claims rejected by the Examiner based on the combination of Brown and Rice depends either directly or indirectly from one of the independent claims rejected by the Examiner under Section 102 in view Brown. In particular, Appellants note that claims 10-11 depend from claim 1, claims 26-27 depend from claim 17, and claims 39-40 depend from claim 33.

As discussed above, Brown clearly fails to disclose several of the features recited by each of independent claims 1, 17, and 33. Furthermore, Appellants submit that Rice fails to obviate the deficiencies of Brown. Indeed, it appears that the

Examiner merely relied upon Rice for teaching inquiry with regard to specific patients. Although Appellants do not necessarily concede that Rice discloses this element, Appellants respectfully submit that this element alone does not overcome the deficiencies of Brown. As such, dependent claims 10-11, 26-27, and 39-40 are believed to be allowable at least by virtue of their dependencies from an allowable base claim.

2. **Request Reversal of the Rejection**

In view of the reasons set forth above, Appellants respectfully request that the Board reverse the rejection of claims 10-11, 26-27, and 39-40 under 35 U.S.C. § 103(a) and instruct the Examiner to allow these claims.

E. **Fifth Ground of Rejection:**

Whether the Examiner has satisfied the burden of establishing a *prima facie* case that claims 12 and 28 are obvious under 35 U.S.C. § 103(a) over Brown in view of Applicant Admitted Prior Art (hereinafter "AAPA").

1. **The Examiner's rejection under 35 U.S.C. § 103 is improper because Brown and AAPA, even in combination, fail to disclose all the recited claim elements, and thus cannot establish a *prima facie* case of obviousness against claims 12 and 28.**

As an initial matter, Appellants traverse the Examiner's assertion that any admissions of prior art have been made. Rather, Appellants note that what is being asserted as AAPA refers to the Examiner's previous use of Official Notice with regard to various database features recited by claims 12 and 28. In the Final Office Action, the Examiner asserted that "Applicant[s] failed to properly traverse the Examiner's assertion" in the previous Office Action. Final Office Action, page 20. Appellants respectfully disagree and submit that that Official Notice with regard to this subject matter was first cited in the Office Action mailed June 21, 2007, and seasonably challenged and traversed by Appellants in the subsequently filed Response. *See* Response to Office Action filed

September 21, 2007, pages 24-25. Thus, contrary to the Examiner's assertion, Appellants respectfully submit to the Board that the Examiner's use of Official Notice was properly traversed in the Response filed September 21, 2007. *See id.* Therefore, the Examiner's classification of the facts taken under Official Notice in the previous Office Action as being admitted prior art in the Final Office Action is improper.

Further, with regard to the use of Official Notice in the instant Office Action, Appellants note that the Examiner has taken Official Notice specifically with regard to the database actions of "(a) forming a query; (b) transmitting the query to the database; (c) parsing of the query by the database; (d) retrieving information stored in the database as indicated by the result of (c); [and] (e) returning the result of (d) for display; is old and well established in the art of database." Final Office Action, page 20. As discussed above, however, Brown clearly fails to disclose several of the features recited by each of independent claims 1, 14, 17, 30, and 33. Furthermore, even if the general database query steps of claims 12 and 28 could be inferred from unidentified art, Appellants submit that what is asserted to be AAPA fails to obviate the deficiencies of Brown. Indeed, it appears that the Examiner merely relied upon AAPA for allegedly teaching these database actions. Therefore, although Appellants do not necessarily concede that AAPA discloses these elements, Appellants respectfully submit that these elements alone do not overcome the deficiencies of Brown. As such, dependent claims 12 and 28 are believed to be allowable at least by virtue of their dependencies from allowable base claims 1 and 17, respectively.

Still further, Appellants again challenge the Examiner's assertion that the previous use of Official Notice constitutes admitted prior art. Even if the general query steps of claims 12 and 28 could be inferred from unidentified art, the Examiner still bears the burden of establishing a *prima facie* case based upon a reasonable combination with Brown and some likelihood of success. In this case, Brown does not disclose entering information into a database in the manner set forth in claims 1 or 17. As such, the query

steps of claims 12 and 28 do not appear combinable with Brown. Thus, the mere citation of Official Notice fails to provide the requisite likelihood of success in this regard, and is therefore traversed.

2. **Request Reversal of the Rejection**

In view of the reasons set forth above, Appellants respectfully request that the Board reverse the rejection of claims 12 and 28 under 35 U.S.C. § 103(a) and instruct the Examiner to allow these claims.

Conclusion

In view of the arguments presented herein, Appellants respectfully submit that all pending claims are in condition for allowance. However, if the Examiner or the Board wishes to resolve any other issues by way of a telephonic conference, the Examiner or Board is kindly invited to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,

Date: September 1, 2008

/Patrick S. Yoder/

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8. **APPENDIX OF CLAIMS ON APPEAL**

1. A method for managing clinical study (CS) information for a clinical research entity via a server system coupled to a centralized database and at least one client system, said method comprising:

receiving at the server system CS information relating to at least one patient involved in a clinical study, the CS information being entered through a user selected template displayed on the client system, wherein the user selected template is selected from a plurality of templates stored in a centralized database, each of the plurality of templates configured to correspond to specific clinical studies;

storing CS information received at the server system in the centralized database;

tracking CS information stored in the centralized database;

updating the centralized database periodically with newly received information to maintain CS information; and

providing CS information in response to an inquiry.

2. A method in accordance with claim 1 further comprising transmitting from the server system to the at least one client system at least one report summarizing information and findings for a clinical study.

3. A method in accordance with claim 1 further comprising transmitting from the server system to the at least one client system at least one report summarizing CS information and findings for at least one patient involved in a clinical study.

4. A method in accordance with Claim 1 further comprising providing at least one medical device in communication with the at least one client system, the at least one medical device includes at least one of a computed tomography device, a radiography device, a positron emission tomography device, and an ultrasound imaging device.

5. A method in accordance with claim 4 wherein receiving CS information comprises:

using a template selected by a user from the plurality of templates stored in the centralized database to gather protocols for operating the at least one medical device;

displaying the template on the client system;

operating the at least one medical device based on the entered protocols; and

receiving at the server system information generated as part of the operation of the at least one medical device including at least one of x-rays and diagnostic images for a patient involved in a clinical study.

6. A method in accordance with claim 1 wherein receiving CS information comprises:

using a template selected by a user from the plurality of templates stored within the centralized database to gather CS information;

displaying the selected template on the client system; and

inputting into the selected template at least one of a patient name, a patient sex, a patient medical history, a patient weight, a patient height, a patient age, a patient ID number, a modality of treatment and/or diagnosis, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents and information relating to the treatment and/or diagnosis patient involved in a clinical study conducted by the clinical research entity.

7. A method in accordance with claim 1 wherein tracking CS information comprises:

compiling a data report including at least one of a patient name, a patient sex, a patient medical history, a patient weight, a patient height, a patient age, a patient ID

number, a modality of treatment and/or diagnosis, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information relating to utilized medical equipment, engineering information relating to utilized medical equipment, marketing information relating to utilized medical equipment, and any other information relating to the treatment and/or diagnosis of a patient involved in a clinical study conducted by the clinical research entity; and

transmitting the data report to a predesignated party at the at least one client system.

8. A method in accordance with claim 1 wherein tracking CS information comprises exporting CS information selected by a user to at least one computer program.

9. A method in accordance with claim 1 wherein tracking CS information further comprises:

linking to a specific patient involved in a clinical study at least one of a patient medical history, utilized medical application information, utilized medical equipment information, treatment diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents and information relating to the treatment and/or diagnosis of the patient; and

displaying on the client system at least one of the patient medical history, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents or information relating to the treatment and/or diagnosis of the patient.

10. A method in accordance with claim 1 wherein providing CS information comprises:

displaying on the client system at least one of a list of patients involved in a clinical study and a list of clinical studies conducted by the clinical research entity;

receiving an inquiry from the client system regarding at least one of a patient included within the patient list and a clinical study included within the clinical study list.

11. A method in accordance with claim 1 wherein providing CS information comprises:

receiving an inquiry from the client system regarding at least one of a patient name, a patient sex, a patient medical history, a patient weight, a patient height, a patient age, a patient ID number, a modality of treatment diagnosis, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents or information relating to the treatment and/or diagnosis of a patient involved in a clinical study conducted by the clinical research entity; and

displaying information on the client system regarding at least one of the patient name, the patient sex, the patient medical history, the patient weight, the patient height, the patient age, the patient ID number, the modality of treatment diagnosis, utilized medical application information, utilized medical equipment information, treatment diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents or information relating to the treatment and/or diagnosis of the patient.

12. A method in accordance with claim 1 wherein providing CS information comprises:

accessing the centralized database;

searching the database regarding the specific inquiry;

retrieving information from the database; and

transmitting the retrieved information to the client system for display by the client system.

13. A method in accordance with claim 1 further comprising connecting the client system and the server system via a network that includes one of a wide area network, a local area network, an intranet and the Internet.

14. A method for managing clinical study (CS) information for a clinical research entity via a server system coupled to a centralized database and at least one client system, the at least one client system in communication with at least one medical device, said method comprising:

using a template selected by a user from a plurality of templates stored in a centralized database to gather protocols for acquisition of image data via the at least one medical device, each of the plurality of templates configured to correspond to specific clinical studies;

operating the at least one medical device for acquiring image data based on the entered protocols;

receiving at the server system CS information that relates to at least one patient involved in a clinical study, the CS information being entered through the user selected template displayed on the client system and being generated as part of the operation of the at least one medical device including acquisition of diagnostic images;

storing CS information received at the server system in the centralized database;

tracking CS information stored in the centralized database;

updating the centralized database periodically with newly received CS information to maintain CS information;

providing CS information in response to an inquiry; and

transmitting from the server system to the at least one client system at least one report relating to CS information and findings for at least one of a clinical study and a patient involved in a clinical study.

15. A method in accordance with claim 14 further comprising providing at least one medical device including at least one of a computed tomography device, a radiography device, a positron emission tomography device, and an ultrasound imaging device.

16. A method in accordance with claim 14 wherein receiving CS information comprises:

receiving at the server system at least one of a patient name, a patient sex, a patient medical history, a patient weight, a patient height, a patient age, a patient ID number, a modality of treatment and/or diagnosis, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents or information relating to the treatment and/or diagnosis of a patient involved in a clinical study conducted by the clinical research entity.

17. A network based system for managing clinical study (CS) information, said system comprising:

a client system comprising a browser;

a centralized database for storing information and a plurality of templates; and

a server system configured to be coupled to said client system and said database, said server system further configured to:

receive CS information relating to at least one patient involved in a clinical study, said CS information being entered through a user selected template displayed on said client system, wherein the user selected template is selected from the plurality of templates stored in the centralized database, each of the plurality of templates configured to correspond to specific clinical studies;

store CS information in said centralized database;

track CS information;

update said centralized database periodically with newly received CS information to maintain CS information; and

provide CS information in response to an inquiry by a user.

18. A system in accordance with claim 17 wherein said server system is further configured to transmit to said client system at least one report summarizing CS information and findings for a clinical study.

19. A system in accordance with claim 17 wherein said server system is further configured to transmit to said client system at least one report summarizing CS information and findings for at least one patient involved in a clinical study.

20. A system in accordance with claim 17 further comprising at least one medical device in communication with said client system and said server system, said at least one medical device including at least one of a computed tomography device, a radiography device, a positron emission tomography device, and an ultrasound imaging device.

21. A system in accordance with claim 20 wherein said server system further comprises a receiving component that:

uses a template selected by a user from said plurality of templates stored in said centralized database to gather protocols for operating said at least one medical device;

displays said selected template on said client system;

operates said at least one medical device based on said entered protocols; and

receives CS information generated as part of the operation of said at least one medical device including at least one of x-rays and diagnostic images for a patient involved in a clinical study.

22. A system in accordance with claim 17 wherein said server system further comprises a receiving component that:

uses a template selected by a user from said plurality of templates stored in said centralized database to gather CS information;

displays said selected template on said client system; and

receives through said selected template at least one of a patient name, a patient sex, a patient medical history, a patient weight, a patient height, a patient-age, a patient ID number, a modality of treatment and/or diagnosis, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents and information relating to the treatment and/or diagnosis of a patient involved in a clinical study conducted by the clinical research entity.

23. A system in accordance with claim 17 wherein said server system further comprises a tracking component that:

compiles a data report including at least one of a patient name, a patient sex, a patient medical history, a patient weight, a patient height, a patient age, a patient ID

number, a modality of treatment and/or diagnosis, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information relating to utilized medical equipment, engineering information relating to utilized medical equipment, marketing information relating to utilized medical equipment, and any other information relating to the treatment and/or diagnosis of a patient involved in a clinical study conducted by the clinical research entity; and

transmits said data report to a predesignated party at said client system.

24. A system in accordance with claim 17 wherein said server system further comprises a tracking component that exports CS information selected by a user to at least one computer program.

25. A system in accordance with claim 17 wherein said server system further comprises a tracking component that:

links to a specific patient involved in a clinical study at least one of a patient medical history, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents and information relating to the treatment and/or diagnosis of said patient; and

displays on said client system at least one of said patient medical history, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents or information relating to the treatment and/or diagnosis of said patient.

26. A system in accordance with claim 17 wherein said server system further comprises a providing component that:

displays on said client system at least one of a list of patients involved in a clinical study and a list of clinical studies conducted by the clinical research entity; and

receives an inquiry from said client system regarding at least one of a patient included within said patient list and a clinical study included within said clinical study list.

27. A system in accordance with claim 17 wherein said server system further comprises a providing component that:

receives an inquiry from said client system regarding at least one of a patient name, a patient sex, a patient medical history, a patient weight, a patient height, a patient age, a patient ID number, a modality of treatment and/or diagnosis, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents or information relating to the treatment and/or diagnosis of a patient involved in a clinical study conducted by the clinical research entity; and

displays information on said client system regarding at least one of said patient name, said patient sex, said patient medical history, said patient weight, said patient height, said patient age, said patient ID number, said modality of treatment and/or diagnosis, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents or information relating to the treatment and/or diagnosis of said patient.

28. A system in accordance with claim 17 wherein said server system further comprises a providing component that:

accesses said centralized database;

searches said database regarding a specific inquiry;

retrieves information from said database; and

transmits said retrieved information to said client system for display by said client system.

29. A system in accordance with claim 17 wherein said server system, said client system, and said database are connected via a network that includes one of a wide area network, a local area network, an intranet and the Internet.

30. A network based system for managing clinical study (CS) information, said system comprising:

a client system comprising a browser;

at least one medical device in communication with said client system;

a centralized database for storing information and a plurality of templates; and

a server system configured to be coupled to said client system and said database, said server system further configured to:

use a template selected by a user from the plurality of templates stored in the centralized database to gather protocols for acquisition of image data via the at least one medical device, each of the plurality of templates configured to correspond to specific clinical studies;

operate said at least one medical device for acquiring image data based on said entered protocols;

receive CS information relating to at least one patient involved in a clinical study, said CS information entered through a user selected template displayed on said client system and generated as part of the operation of said at least one medical device including acquisition of diagnostic images;

store CS information in said centralized database;

track CS information;

update said centralized database periodically with newly received CS information to maintain CS information;

provide CS information in response to an inquiry; and

transmit to said client system at least one report relating to CS information and findings for at least one of a clinical study and a patient involved in a clinical study.

31. A system in accordance with claim 30 wherein said at least one medical device comprises at least one of a computed tomography device, a radiography device, a positron emission tomography device, and an ultrasound imaging device.

32. A system in accordance with claim 30 wherein said server system further comprises a receiving component that:

receives at least one of a patient name, a patient sex, a patient medical history, a patient weight, a patient height, a patient age, a patient ID number, a modality of treatment and/or diagnosis, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents or information relating to the treatment and/or diagnosis of a patient involved in a clinical study conducted by the clinical research entity.

33. A computer program embodied on a computer readable medium for managing clinical study (CS) information, said program comprising a code segment that:

receives CS information relating to at least one patient involved in a clinical study through a user selected template displayed on a client system, wherein the user selected

template is selected from a plurality of templates stored in a centralized database, each of the plurality of templates configured to correspond to specific clinical studies;

maintains a database by adding, deleting and updating CS information; tracks CS information;

provides CS information in response to an inquiry by a user; and

transmits to said client system at least one report summarizing CS information and findings relating to at least one of a clinical study and a patient involved in a clinical study.

34. A computer program in accordance with claim 33 further comprising a code segment that enables at least one medical device to communicate with said client system wherein said at least one medical device includes at least one of a computed tomography device, a radiography device, a positron emission tomography device, and an ultrasound imaging device.

35. A computer program in accordance with claim 34 further comprising a code segment that:

displays a template selected by a user on said client system;

uses said selected template to gather protocols for operating said at least one medical device;

operates said at least one medical device based on said entered protocols; and

receives CS information generated as part of the operation of said at least one medical device including at least one of x-rays and diagnostic images.

36. A computer program in accordance with claim 33 further comprising a code segment that:

displays a template selected by a user on said client system;

uses said selected template to gather CS information; and

receives through said selected template at least one of a patient name, a patient sex, a patient medical history, a patient weight, a patient height, a patient age, a patient ID number, a modality of treatment and/or diagnosis, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents and information relating to the treatment and/or diagnosis of a patient involved in a clinical study conducted by the clinical research entity.

37. A computer program in accordance with claim 33 further comprising a code segment that:

compiles a data report including at least one of a patient name, a patient sex, a patient medical history, a patient weight, a patient height, a patient age, a patient ID number, a modality of treatment and/or diagnosis, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information relating to utilized medical equipment, engineering information relating to utilized medical equipment, marketing information relating to utilized medical equipment, and any other information relating to the treatment and/or diagnosis of a patient involved in a clinical study conducted by the clinical research entity; and

transmits said data report to a predesignated party at said client system.

38. A computer program in accordance with claim 33 further comprising a code segment that:

links to a specific patient involved in a clinical study at least one of a patient medical history, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering

information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents and information relating to the treatment and/or diagnosis of said patient; and

displays on said client system at least one of said patient medical history, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays; manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents or information relating to the treatment and/or diagnosis of said patient.

39. A computer program in accordance with claim 33 further comprising a code segment that:

displays on said client system at least one of a list of patients involved in a clinical study and a list of clinical studies conducted by the clinical research entity; and

receives an inquiry from said the client system regarding at least one of a patient included within said patient list and a clinical study included within said clinical study list.

40. A computer program in accordance with claim 33 further comprising a code segment that:

receives an inquiry from said client system regarding at least one of a patient name, a patient sex, a patient medical history, a patient weight, a patient height, a patient age, a patient ID number, a modality of treatment and/or diagnosis, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents or information relating to the treatment

and/or diagnosis of the patient involved in a clinical study conducted by the clinical research entity;

and displays information on said the client system regarding at least one of said patient name, said patient sex, said patient medical history, said patient weight, said patient height, said patient age, said patient ID number, said modality of treatment and/or diagnosis, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents or information relating to the treatment and/or diagnosis of said patient.

9. **APPENDIX OF EVIDENCE**

Exhibit A:

Definition 6 of "protocol." ***Random House Dictionary of the English Language, Unabridged***, 2nd ed., page 1555 (1987).

10. **APPENDIX OF RELATED PROCEEDINGS**

None.

EXHIBIT A

THE RANDOM HOUSE DICTIONARY OF THE ENGLISH LANGUAGE

Second Edition

Unabridged

chaeopteryx hy an eetimated 75 million years. [< NL (1986), equiv. to Gk *proto-* PROTO- + L *avis* bird]

pro·to·chor·date (prō′tō kôr′dāt), *n. Zool.* any of the nonvertebrate chordates, ae the tunicates, cephalochordates, and hemichordatee. [1890–95; < NL *Protochordata* name of the group; see PROTO-, CHORDATE]

pro·to·col (prō′te kôl′, -kol′, -kōl′), *n.* **1.** the customs and regulations dealing with diplomatic formality, precedence, and etiquette. **2.** an original draft, minute, or record from which a document, esp. a treaty, is prepared. **3.** a supplementary international agreement. **4.** an agreement between states. **5.** an annex to a treaty giving data relating to it. **6.** *Med.* the plan for carrying out a scientific study or a patient's treatment regimen. **7.** *Computers.* a set of rules governing the format of messages tbat are exchanged between computers. **8.** Aleo called **pro′tocol state′ment, pro′tocol sen′tenca, pro′tocol proposi′tion.** *Philos.* a statement reporting an observation or experience in the most fundamental terms without interpretation: sometimes taken as the basis of empirical verification, as of scientific laws. —*v.i.* **9.** to draft or issue a protocol. [1535–45; earlier *protocoll* < ML *prōtocollum* < LGk *prōtókollon* orig., a leaf or tag attached to a rolled papyrus manuscript and containing notes es to contents. Ses PROTO-, COLLOIN] —**pro·to·col·ar** (prō′ta kol′er), **pro·to·col′a·ry, pro′to·col′ic,** *adj.*

pro·to·con·ti·nent (prō′tō kon′tn ent), *n. Geol.* an actual or hypothetical landmass that might later be enlarged into a major continent or broken up into smaller onee. [1955–60; PROTO- + CONTINENT]

pro·to·dea·con (prō′tō dē′kən), *n.* a chief deacon in the Greek Church. [1690–1700; PROTO- + DEACON]

pro·to·derm (prō′te dûrm′), *n. Bot.* a thin outer layer of the meristem in embryos and growing points of roots and etems, which gives rise to the epidermis. Also called **dermatogen.** [1930–35; PROTO- + -DERM]

pro·to-Dor·ic (prō′tō dôr′ik, -dor′-), *adj.* of or pertaining to architecture, as in certain Egyptian tombs, supposedly anticipating the Grecian Doric order. [1875–80]

pro·to-E·lam·ite (prō′tō ē′le mīt′), *n.* the indigenous script of Elam, found on inscriptions and tablets from the fourth millennium B.C.

pro·to-form (prō′tō fôrm′), *n. Ling.* a hypothetical linguistic form reconstructed as an element of a protolanguage. [1960–65]

pro·to·gal·ax·y (prō′tō gal′ak sē, prō′tō gal′-), *n., pl.* **-ax·ies.** *Astron.* the large concentration of gas and dust from which a galaxy is formed. [1945–50; PROTO- + GALAXY]

Pro·to·ge·ni·a (prō′tə jə nī′ə), *n. Class. Myth.* the first woman born efter the great flood of Zeus, daughter of Deucalion and Pyrrha. Also, **Pro·to·ge·ne·a** (prō′tə-jə nē′ə).

Pro·to·ge·o·met·ric (prō′tō jē′ə me′trik), *adj.* (*sometimes l.c.*) pertaining to or designating a style of vase painting developed in Greece chiefly during the 10th century B.C. and characterized by use of abstract geometrical motifs. Also, **Pro′to-ge′o·met′ric, pro′to-ge′·o·mat′ric, Pro′to-Ge′o·met′ric.** Cf. **geometric** (def. 4). [1925–30; PROTO- + GEOMETRIC]

Pro·to-Ger·man·ic (prō′tō jər man′ik), *n.* **1.** the unattested prehietoric parent language of the Germanic languages; Germanic. —*adj.* **2.** of or pertaining to Proto-Germanic.

pro·to·his·to·ry (prō′tō his′tə rē, -his′trē), *n., pl.* **-ries. 1.** a branch of study concerned with the transition period betweeen prehistory and the earliest recorded hietory. **2.** the period in a culture immediately before its recorded history begins. [1915–20; PROTO- + HISTORY] —**pro·to·his·to·ri·an** (prō′tō hi stôr′ē ən, -stōr′-), *n.* —**pro·to·his·tor·ic** (prō′tō hi stôr′ik, -stor′-), **pro′to·his·tor′i·cal,** *adj.*

pro·to·hu·man (prō′tō hyōō′mən or, *often,* -yōō′-), *adj.* **1.** of, pertaining to, or resembling extinct hominid populations that had some but not all the features of modern *Homo sapiens.* —*n.* **2.** a protohuman animal. [1905–10; PROTO- + HUMAN]

Pro·to-In·do-Eu·ro·pe·an (prō′tō in′dō yŏŏr′ə pē′-ən), *n.* **1.** the unattested prehistoric parent language of the Indo-European languages; Indo-European. —*adj.* **2.** of or pertaining to Proto-Indo-European.

pro·to-I·on·ic (prō′tō ī on′ik), *adj.* of or pertaining to architecture supposedly anticipating the Grecian Ionic order. [1885–90]

pro·to·lan·guage (prō′tō leng′gwij), *n. Ling.* the reconstructed or poetulated perent form of a language or a group of related languages. [1945–50; PROTO- + LANGUAGE]

pro·to·lith·ic (prōt′l ith′ik), *adj. Anthropol.* noting or pertaining to stone implements selected according to suitability of the form to a particular purpose without definite shaping on the part of the user. [1895–1900; PROTO- + LITHIC]

pro·to·log (prōt′l ôg′, -og′), *n. Biol.* the original description of a species, genus, etc. Also, **pro′to·logue′.** [1900–05; PROTO- + (CATA)LOG]

pro·to·mar·tyr (prō′tō mär′tər), *n.* **1.** the first Christian martyr, Saint Stephen. **2.** the first martyr in any cause. [1400–50; late ME *prothomartyr* < LL *prōtomartyr* < LGk *prōtómartys.* See PROTO-, MARTYR]

pro·to·mor·phic (prō′tə môr′fik), *adj. Biol.* having a primitive character or structure. [1855–60; PROTO- + -MORPHIC] —**pro′to·morph′,** *n.*

pro·ton (prō′ton), *n. Physics, Chem.* a positively charged elementary particle that is a fundamental constituent of all atomic nuclei. It is the lightest and most stable baryon, having a charge equal in magnitude to that of the electron, a spin of ½, and a mass of 1.673×10^{-27} kg. *Symbol:* P [1915–20; n. use of Gk *prôton,* neut. of *prôtos* FIRST] —**pro·ton′ic,** *adj.*

pro·to·ne·ma (prō′tə nē′mə), *n., pl.* **-ma·ta** (-mə tə). *Bot.* a primary, usually filamentous structure produced hy the germination of the spore in mosses and certain related plants, and from which the leafy plant whicb bears the sexual organs arises as a lateral or terminal shoot. [1855–60; < NL < Gk *prōto-* PROTO- + *nêma* thread] —**pro′to·ne′mal,** *adj.*

pro′ton num′ber. See **atomic number.**

pro·ton·o·tar·y (prō ton′ə ter′ē, prōt′n ō′tə rē), *n., pl.* **-tar·ies.** prothonotary. —**pro·ton′o·tar′y·ship′,** *n.*

pro′ton-pro′ton chain′ (prō′ton prō′ton), *Physics., Astron.* a series of thermonuclear reactions, responsible for the energy production in stars like the sun, in which the nuclei of hydrogen atoms are transformed into helium nuclei hy sequential addition of single hydrogen nuclei.

pro′ton syn′chrotron, *Physics.* a synchrotron used for accelerating protons. [1945–50]

pro·to·path·ic (prō′tə path′ik), *adj. Physiol.* **1.** noting or pertaining to a general, nondiscriminating responsiveness to pain or temperature stimuli (opposed to *epicritic*). **2.** primitive; primary. [1855–60; PROTO- + -PATHIC] —**pro·top·a·thy** (prə top′ə thē), *n.*

pro·to·pec·tin (prō′tə pek′tin), *n. Biochem.* any of the class of water-insoluble pectic substances that are found in the rind of citrus fruits or in apple peels and that are hydrolyzed to pectin or pectic acid. Also called **pectinogen, pectose.** [1905–10; PROTO- + PECTIN]

pro·to·phlo·em (prō′tə flō′em), *n. Bot.* the part of the primary phloem that develops first, consisting of narrow, thin-walled cells. [1880–85; PROTO- + PHLOEM]

pro·to·plan·et (prō′tō plan′it), *n. Astron.* the collection of matter, in the process of condensation, from which a planet is formed. [1945–50; PROTO- + PLANET]

pro·to·plasm (prō′tə plaz′əm), *n.* **1.** *Biol.* (no longer in technical use) the colloidal and liquid substance of which cells are formed, excluding horny, chitinous, and other structural material; the cytoplasm and nucleus. **2.** *Obs.* the living matter of organisms regarded as the physical basis of life, having the ability to sense and conduct stimuli. [1840–50; < NL *prōtoplasma.* See PROTO-, -PLASM] —**pro′to·plas′mic, pro′to·plas′mal, pro·to·plas·mat·ic** (prō′tō plaz mat′ik), *adj.*

pro·to·plast (prō′tə plast′), *n.* **1.** *Biol.* **a.** the contents of a cell within tbe cell membrane, considered as a fundamental entity. **b.** the primordial living unit or cell. **2.** a person or thing that is formed first; original; prototype. **3.** the hypothetical first individual or one of the supposed first pair of a species or the like. [1525–35; < LL *prōtoplastus* the first man, n. use of Gk *prōtóplastos* formed first. See PROTO-, -PLAST] —**pro′to·plas′tic,** *adj.*

pro·top·o·dite (prō top′ə dīt′), *n. Zool.* the basal portion of a two-branched crustacean leg or other appendage. Also, **pro·to·pod** (prō′tə pod′). Cf. **endopodite, exopodite.** [1865–70; PROTO- + POD- + -ITE¹] —**pro·top·o·dit·ic** (prə top′ə dit′ik), *adj.*

pro·to·popa (prō′tə pōp′), *n.* the ranking priest in a cathedral of the Eastern Church. Also called **protopresbyter.** [1655–65; < Russ *protopóp* < LGk *protopapâs.* See PROTO-, POPE]

pro·to·pres·by·ter (prō′tō prez′hi tər, -pres′-), *n. Eastern Ch.* **1.** a title given to distinguished priests. **2.** protopope. [1880–85; < MGk *prōtopresbýteros.* See PROTO-, PRESBYTER]

pro·to·star (prō′tō stär′), *n. Astron.* en early stage in the evolution of a star, after the beginning of the collapse of the gas cloud from which it is formed, but before sufficient contraction has occurred to permit initiation of nuclear reactions at its core. [1945–50; PROTO- + STAR]

pro·to·stale (prō′tə stēl′, -stē′lē), *n. Bot.* the solid stele of most roots, having a central core of xylem enclosed hy phloem. [1900–05; PROTO- + STELE] —**pro·to·ste·lic** (prō′tə stē′lik), *adj.*

pro·to·stome (prō′tə stōm′), *n. Zool.* any member of the lower invertebrate phyla in which the mouth appears before the anus during development, cleavage is spiral and determinate, and the coelom forms as a splitting of the mesoderm. Cf. **deuterostome.** [PROTO- + -STOME]

pro·to·the·ri·an (prō′tə thēr′ē ən), *adj.* **1.** belonging or pertaining to the group Prototheria, comprising the monotremes. —*n.* **2.** a prototherian animal. [1880–85; < NL *Prototheri*(*a*) (< Gk *prōto-* PROTO- + *thēría,* pl. of *thēríon* beast) + -AN]

pro·to·troph (prō′tə trof′, -trōf′), *n. Biol.* **1.** a microorganism that has the same nutritional requirements as the parent organism. Cf. **auxotroph. 2.** an organism or cell capable of synthesizing all its metabolites from inorganic material, requiring no organic nutrients. [1945–50; back formation from PROTOTROPHIC]

pro·to·troph·ic (prō′tə trof′ik, -trō′fik), *adj.* **1.** (esp. of certain bacteria) requiring only inorganic substances for growth. **2.** (of certain microorganisms) requiring no specific nutriments for growth. [1895–1900; PROTO- + -TROPHIC]

pro·to·type (prō′tə tīp′), *n., v.* **-typed, -typ·ing.** —*n.* **1.** the original or model on which something is based or formed. **2.** someone or something that serves to illustrate the typical qualities of a class; model; exemplar: *She is the prototype of a student activist.* **3.** something analogous to another thing of a later period: *a Renaissance prototype of our modern public housing.* **4.** *Biol.* an archetype; a primitive form regarded as the basis of a group. —*v.t.* **5.** to create the prototype or an experimental model of: *to prototype a solar-power car.* [1595–1605; < NL *prōtotypon* < Gk *prōtótypon,* n. use of neut. of *prōtótypos* original. See PROTO-, TYPE] —**pro′to·typ′·al, pro·to·typ·i·cal** (prō′tə tip′i kəl), **pro′to·typ′ic,** *adj.* —**pro′to·typ′i·cal·ly,** *adv.*
—**Syn. 1.** pattern.

pro·tox·ide (prō tok′sīd, -sid), *n. Chem.* the one of a series of oxides having the smallest proportion of oxygen. Also, **pro·tox·id** (prō tok′sid). [PROT- + OXIDE]

pro·to·xy·lem (prō′tə zī′ləm, -lem), *n. Bot.* the part of the primary xylem that develops first, consisting of narrow, thin-walled cells. [1895–1900; PROTO- + XYLEM]

Pro·to·zo·a (prō′tə zō′ə), *n.* a major grouping or superphylum of the kingdom Protista, comprising the protozoans. [1825–35; < NL; see PROTO-, -ZOA]

pro·to·zo·an (prō′tə zō′ən), *n., pl.* **-zo·ans,** (*esp. collectively*) **-zo·a** (-zō′ə), *adj. Biol.* —*n.* **1.** any of a diverse group of eukaryotes, of the kingdom Protiste, thet ars primarily unicellular, existing singly or aggregating into colonies, are usually nonphotoeynthetic, and are often classified further into phyla according to their capacity for and msans of motility, as by pseudopods, flagella, or cilia. —*adj.* **2.** of, pertaining to, or characteristic of a protozoan. [1880–85; PROTOZO(A) + -AN]

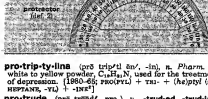
pro·to·zo·on (prō′tə zō′on, -ən), *n., pl.* **-zo·a** (-zō′ə). protozoan. [sing. of PROTOZOA]

pro·tract (prō trakt′, prə-), *v.t.* **1.** to draw out or lengthen, esp. in time; extend the duration of; prolong. **2.** *Anat.* to extend or protrude. **3.** (in surveying, mathematics, etc.) to plot and draw (lines) with a scale and a protractor. [1540–50; < L *prōtroctus* (ptp. of *prōtrohere* to draw forth, prolong). See PRO-¹, TRACT¹] —**pro·tract′ed·ly,** *adv.* —**pro·tract′ed·ness,** *n.* —**pro·tract′i·ble,** *adj.* —**pro·trac′tive,** *adj.*
—**Syn. 1.** continue. See **lengthen.** —**Ant. 1.** curtail.

pro·trac·tile (prō trak′til, -tīl, prə-), *adj.* capable of being protrected, lengthened, or protruded. [1820–30; PROTRACT + -ILE] —**pro′trac·til′i·ty,** *n.*

pro·trac·tion (prō trak′shən, prə-), *n.* **1.** the ect of protracting; prolongation; extension. **2.** protrusion. **3.** something that ie protracted. **4.** a drawing or rendering to scala. [1525–35; < LL *prōtractiōn-* (s. of *prōtractiō*) prolongation. See PROTRACT, -ION]

pro·trac·tor (prō trak′tər, prə-), *n.* **1.** a person or thing that protracts. **2.** (in surveying, mathematics, etc.) an instrument having a graduated arc for plotting or measuring angles. **3.** *Anat.* a muscle that causes a part to protrude. [1605–15; < ML; see PROTRACT, -TOR]



protractor (def. 2)

pro·trip·ty·line (prō trip′tl ēn′, -in), *n. Pharm.* a white to yellow powder, $C_{19}H_{21}N$, used for the treetment of depression. [1960–65; PRO(PYL) + TRI- + (*he*)*ptyl* (see HEPTANE, -YL) + -INE²]

pro·trude (prō trōōd′, prə-), *v.,* **-trud·ed, -trud·ing.** —*v.i.* **1.** to project. —*v.t.* **2.** to thrust forward; cause to project. [1610–20; < L *prōtrūdere* to thrust forward, equiv. to *prō-* PRO-¹ + *trūdere* to thrust] —**pro·trud′·ent,** *adj.* —**pro·tru·si·ble** (prō trōō′sə bəl, -zə-, prə-), **pro·trud′a·ble,** *adj.*
—**Syn. 1.** bulge, swell, belly.

pro·tru·sile (prō trōō′sil, -sīl, prə-), *adj.* capable of being thrust forth or extended, as the tongue of a hummingbird. [1840–50; < L *prōtrūs*(*us*) (ptp. of *prōtrūdere* to PROTRUDE) + -ILE]

pro·tru·sion (prō trōō′zhən, prə-), *n.* **1.** the act of protruding or the etate of being protruded. **2.** something that protrudes or projects. [1640–50; < L *prōtrūs*(*us*) (ptp. of *prōtrūdere* to PROTRUDE) + -ION]
—**Syn. 2.** jut, projection, hulge, protuberance.

pro·tru·sive (prō trōō′siv, prə-), *adj.* **1.** projecting or protuberant; thrusting forward, upward, or outward. **2.** obtrusive. **3.** *Archaic.* pushing forward; having propulsive force. [1670–80; < L *prōtrūs*(*us*) (ptp. of *prōtrūdere* to PROTRUDE) + -IVE] —**pro·tru′sive·ly,** *adv.* —**pro·tru′sive·ness,** *n.*

pro·tu·ber·ance (prō tōō′bər əns, -tyōō′-, prə-), *n.* **1.** the condition, state, or quality of being protuberant. **2.** a protuberant part or thing; projection or bulgs. [1640–50; PROTUBER(ANT) + -ANCE] —**pro·tu·ber·an·tial** (prō tōō′bə ran′shəl, -tyōō′-), *adj.*
—**Syn. 2.** protrusion, swelling.

pro·tu·ber·an·cy (prō tōō′bər ən sē, -tyōō′-, prə-), *n., pl.* **-cies.** protuberance. [1645–55; PROTUBER(ANT) + -ANCY]

CONCISE PRONUNCIATION KEY: act, cāpe, dâre, pärt; set, ēqual; if, īce; ox, ōver, ôrder, oil, bŏŏk, bōōt, out; up, ûrge; child; sing; shoe; thin, *that;* zh as in *treasure.* ə = *a* as in *alone, e* as in *system, i* as in *easily, o* as in *gallop, u* as in *circus;* ᵊ as in *fire* (fīᵊr), *hour* (ouᵊr). l and n can serve as syllabic consonants, as in *cradle* (krād′l), and *button* (but′n). See the full key inside the front cover.

pro′re·stric′tion, *adj.*
pro′re·vi′sion, *adj.*
pro′rev·o·lu′tion, *adj.*
pro′rev·o·lu′tion·ar′y, *adj.*
pro′rev·o·lu′tion·ist, *adj., n.*
pro·rit′u·al, *adj.*
pro′ro·man′tic, *adj.*
pro′ro·man′ti·cism, *n.*
pro′-Ru·ma′ni·an, *adj., n.*
pro-Rus′sian, *adj., n.*
pro′-Scan·di·na′vi·an, *adj.*
pro′scho·las′tic, *adj.*
pro′scho·las′ti·cism, *n.*
pro·sci′ance, *adj.*
pro′sci·en·tif′ic, *adj.*
pro-Scrip′tur·al, *adj.*
pro-Scrip′ture, *adj.*
pro·se′cre·cy, *adj.*
pro·slave′, *adj.*
pro′-So·ma′li·a, *adj.*
pro-South′, *adj.*
pro-South′ern, *adj.*
pro-So′vi·et, *adj.*
pro-Spain′, *adj.*
pro-Span′ish, *adj.*